



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/722,737

11/25/2003

Bradley S. Galer

BSG 021 US

7300

35812 7590 02/17/2010

GUY DONATIELLO  
ENDO PHARMACEUTICALS  
100 Endo Boulevard  
CHADDS FORD, PA 19317

EXAMINER

ARNOLD, ERNST V

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

02/17/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Interview Summary</b>	<b>Application No.</b> 10/722,737	<b>Applicant(s)</b> GALER, BRADLEY S.	
	<b>Examiner</b> ERNST V. ARNOLD	<b>Art Unit</b> 1616	

All participants (applicant, applicant's representative, PTO personnel):

(1) ERNST V. ARNOLD. (3) \_\_\_\_.

(2) Peter Long. (4) \_\_\_\_.

Date of Interview: 07 January 2009.

Type: a) ☒ Telephonic    b) ☐ Video Conference  
c) ☐ Personal [copy given to: 1) ☐ applicant    2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes    e) ☐ No.  
If Yes, brief description: \_\_\_\_.

Claim(s) discussed: 1.

Identification of prior art discussed: Hind US 5411738; Rowbotham Brain 1996.

Agreement with respect to the claims f) ☐ was reached.    g) ☒ was not reached.    h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/Ernst V Arnold/ Primary Examiner, Art Unit 1616	
---	--

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: 1) Applicant's representative started the discussion by identifying himself as the attorney of record and presented their position on the cited references. With respect to the 102 rejection, Hind US 5411738, it is Applicant's position that post herpetic neuralgia is associated with pain and not numbness and directed the Examiner's attention to Figure 3 on page 350 of Rowbotham for support. The Figure showed thermal sensory deficits and that some subjects had positive values and some had negative values. Applicant's interpretation of the Figure is that not all patients have all the symptoms. Please note that 'numbness' was not measured in the Figure. Applicant's representative further stated that the Medline reference, which teaches numbness as a symptom of post herpetic neuralgia, is in contradiction to the art and Rowbotham. The Examiner could not agree. Rowbotham clearly states on page 347 bottom that in patients with post herpetic neuralgia demonstrated deficits in the perception of single gentle touches, pinprick, heat and cold which were greatest in the centre of the painful area. Applicant defines the negative sensory phenomena such as numbness as the decreased ability to feel light touch [0011]. Rowbotham unquestionably ties post herpetic neuralgia with a deficit in the perception of gentle touches. Therefore, while it is understood that not all patients will experience the same symptoms it is clear that a deficit in the perception of gentle touches, which Applicant defines as the negative sensory phenomena numbness, is a symptom of postherpetic neuralgia and is experienced by some fraction of this patient population. The instant claims do not exclude this patient population fraction. Therefore, identification of a person suffering from post herpetic neuralgia and applying the lidocaine topically to the site of the pain reads on the instant claims because it will inherently treat the negative sensory phenomena. 2) Applicant's representative asserted that it was improper to use Hind in a 103 rejection because "if it is inherent then it can't be obvious." The Examiner cannot agree. Anticipation is the epitome of obviousness. Applicant's representative asserted that the evidenciary references cannot be used in a 103 rejection. This is incorrect. The references establish what is known in the art and have been properly cited and applied. 3) Applicant's representative inquired if the Examiner could indicate allowable subject matter. The Examiner cannot do so at this time. 4) Since the Examiner and Applicant's representative are at an impasse concerning the interpretation of Hind, the Examiner suggested that he would discuss with either his SPE or a QAS this case and the issues at hand and report back to Applicant that discussion. 5) The Examiner consulted with Johnny Railey a patent quality assurance specialist on these issues on the same day. Johnny Railey is in agreement with the examiner that once one of ordinary skill in the art performs the method of Hind to treat post herpetic neuralgia with the topically applied anesthetic then one is simultaneously treating numbness as a recognized part of the pathology. Thus, the anticipation rejection is proper. the Examiner left a voicemail for Applicant with the result of that discussion.